No. 87-822

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IN THE

Supreme Court of the United States

October Term, 1987

FONAR CORPORATION and DR. RAYMOND DAMADIAN,
Petitioners,

vs.

JOHNSON & JOHNSON and TECHNICARE CORPORATION,
Respondents.

BRIEF FOR RESPONDENTS IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

STEPHEN B. JUDLOWE
HOPGOOD, CALIMAFDE, KALIL,
BLAUSTEIN & JUDLOWE
60 East 42nd Street
New York, New York 10165
(212) 986-2480
Attorneys for Respondents

Of Counsel:
FRANCIS J. MURPHY
EVE KUNEN
HOPGOOD, CALIMAFDE, KALIL,
BLAUSTEIN & JUDLOWE
60 East 42nd Street
New York, New York 10165

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The Petition for a Writ of Certiorari is premised on supposed nice distinctions among the judicial Circuits regarding the evidence considered in determining a motion for judgment notwithstanding the verdict. The trial court granted JNOV holding the Damadian patent in suit not infringed.

Petitioners seek *here* a rule that only the evidence offered by the party opposing JNOV be considered for sufficiency to compel judgment on the jury verdict. However, at the trial level when opposing JNOV, and again on

appeal before the Court ofAppeals for the Federal Circuit, petitioners argued for a standard they attack here, *viz.*, that all the evidence be considered in determining whether a jury verdict can stand.

In any event, the CAFC observed in affirming the Judgment of Judge Keeton:

> "We conclude that the district court correctly determined that *no* evidence, and thus no substantial evidence, supports a finding that users of J&J's machine practice the method of claims 1 and 2 of the '832 patent. The jury's verdict that J&J infringed and induced infringement of those claims therefore cannot stand." (Emphasis in original). 821 F.2d at 631; PA. *8a.

Thus, there is no possible judicial approach to Rule 50(b) judgment notwithstanding the verdict which would help these petitioners.

Respondents Johnson & Johnson and Technicare Corporation** oppose the Petition for Writ of Certiorari requested in this case.

Statement of the Case

A. The Patent And Its Subject

Nuclear Magnetic Resonance

Nuclear magnetic resonance ("NMR") is a physical phenomenon known and employed for years before the patent in suit as a tool for chemical analysis. In brief, in an NMR measurement, a static magnetic field of fixed

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* Appendix to the Petition here.

** Subsidiaries and affiliates of Johnson & Johnson are listed in the Brief For Defendants-Appellees in Appeal No. 86-1005 in the United States Court of Appeals For The Federal Circuit.

strength is applied to a specimen to be evaluated causing the nuclei of selected atoms (of interest here, hydrogen) in the specimen to align with the static field direction. The specimen is then exposed to an electromagnetic field of suitable radio frequency oriented perpendicularly to the static field for a brief (pulsed) period. The hydrogen nuclei in the sample absorb radio frequency energy and their axes rotate ("tip") to an unstable excited state pointing in a direction different from the static field direction.* (Lufkin [petitioner's expert witness] A. 449a-457a;** Damadian [patentee and a co-petitioner] A. 67a; PX-439A-C at E. 601-603).

When the brief radio frequency field terminates, the excited (tipped) hydrogen nuclei precess (like gyroscopes or tops) about the static field axis while progressively surrendering energy. The nuclei ultimately return to their base state realigned with the static field. An electrical pick up (receiver) coil provides an electrical output signal measuring this excited nuclei decay. Two different measurements of the *time* it takes for the excited nuclei to surrender their absorbed energy are called T_1 (or,"spin-

* The angular departure ("tipping") of the excited nuclei axes from the static field direction is dependent upon the amplitude and duration of the orthogonal electromagnetic field. The radio frequency excitation is thus referred to as a "90° pulse", a "180°pulse" or the like to indicate the degree of angular rotation or tipping of the nuclei away from the original static field direction (Damadian S.A. 6-7; Lufkin A. 455a-457a, 598a-599a; the patent at 4/37-41 or 60-64, E. 5; E. 750 and 751).

** References in the form "A.—" or "S.A.—" are to the designated pages of the Joint Appendix or Supplemental Appendix, respectively. References to "E. —" are to the Joint Exhibit Appendix.

lattice") and T_2 (or "spin-spin")* in NMR parlance and in the Damadian '832 patent. T_1 and T_2 are separately measured by an NMR instrument. (Damadian A. 67a-68a, 207a-208a, 244a-246a, S.A. 16-23; Lufkin A. 458a, 590a-601a, 605a-606a, 610a-611a, 701a-704a, 707a-708a; PX-217 at E. 198-201).

The numerical values of T_1 and of T_2 (illustratively, each a fraction of a second) measured for a specimen provide information about how (i.e., in what physical state) the NMR-interrogated atoms (hydrogen) are contained in the sample. The T_1 and T_2 relaxation times vary depending upon the degree of motional freedom between nuclei. (Damadian S.A. 8-9; Lufkin S.A. 33-37; the '832 patent 2/13-18, E. 4).

All of this was known *decades* prior to any work of Damadian. NMR instruments were standard fare in laboratories for years pre-Damadian. (Damadian A. 69a, 196a, S.A. 5 and 9; Ling (a petitioners' expert) S.A. 89; the '832 patent, 4/34-37, E. 5).

(ii) *The '832 Patent In Suit And The Underlying Damadian Work*

A colleague of Dr. Damadian, Dr. Freeman W. Cope, had used NMR analysis as a tool to examine tissue. (Damadian A. 61a; Lufkin S.A. 33-37; PX-22, E. 28-31; S.A. 108 discussed below). Dr. Damadian, Cope (and others) had done considerable work on the nature of water structure, i.e., the degree of motional freedom of water molecules within cells. (Damadian A. 58a-59a, 203a, S.A. 10-13;

* T_1 and "spin-lattice", and T_2 and "spin-spin" are interchangeable synonyms in the '832 Damadian patent and in the NMR literature (before and after Damadian). (Damadian A. 68a, 208a, 238a; Lufkin A. 598a, 702a-704a).

S.A. 108-131 discussed below; Ling S.A. 84-88, 90-107). Dr. Damadian, becoming aware of Cope's tissue NMR measurements circa 1969* postulated that the NMR T_1 and T_2 relaxation times might be different for cancerous than for healthy tissue. If so, the T_1 and T_2 relaxation time measurements might serve as a basis for detecting cancer.

To test this hypothesis, Dr. Damadian induced two types of cancerous tumors in several test rats. He then traveled to NMR Specialties, Inc., New Kensington, Pennsylvania where he measured the T_1 NMR relaxation time for malignant and non-malignant tissue excised from the rats using a standard commercial NMR spectrometer available at that firm. (The '832 patent, at column 3, lines 52-59 (herein "3/52-59") and 4/34-41, E. 5).

The T_1 relaxation times for normal tissue are contained in the "T_1" columns of Table 1 of the '832 patent, and the NMR measured T_1 times for malignant tissue are reported in the "T_1" column of Table 2 of the '832 patent. (Damadian S.A. 14-23; A. 244a-246a; Lufkin A. 701a-704a, 707a-708a; the '832 patent, E. 6).**

Similarly, T_2 was measured on by then standard NMR equipment (patent, at 4/33-37 and 61-64, E. 5). The data taken is recorded in the "T_2" columns for the sacrificed rats in Table 1 (normal tissue) and Table 2 (malignant tissue)

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* Dr. Damadian had no previous experience with NMR measurements (A. 72a).

** As the patent notes (4/33-41), T_1 was measured by the prior art radio frequency pulse sequence of a 180° tipping field pulse followed by a 90° pulse until a zero amplitude response is detected. The value of the NMR signal response (amplitude) is irrelevant for such T_1 measurements and thus forms no part of the cancer screen disclosed in the patent. (Lufkin A. 616a-623a esp. 616a-617a, 725a).

of the patent. (Damadian S.A. 14-23; Lufkin A. 701a-704a, 707a-708a; the '832 patent, E. 6).*

Based on the recorded data, Dr. Damadian concluded that the T_1 and T_2 relaxation times for malignant tissue (0.736 seconds and 0.100 seconds, respectively, for Walker sarcoma and slightly higher [0.826 seconds and 0.118 seconds, respectively] for Novikoff hepatoma, patent Table 2, E. 6) were substantially longer than the corresponding times for non-malignant tissue (0.293 seconds and 0.052 seconds, respectively, Table 1 and the patent, 5/59-6/33, E. 6). The essence of the patent is to use this discovery as a screen (test or marker) for cancer, i.e., a "firm basis for decision . . . as to whether cancer is present" (the patent, 1/19-20); "quantitative detection of cancer" (1/25); "rapid screening of cancer" (1/28); as contrasted with "qualitative" cancer detection by image analysis (patent, at 1/17-21).**

The patent claims accord with the discovery as Dr. Damadian perceived it and with the patent specification. Independent claim 1 at issue recites the method of detecting cancer by measuring† the T_1 and T_2 NMR relaxation times

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* T_2 was determined by the known 90°-180° r.f. tipping pulse sequence, measuring T_2 from the time constant of the graph of the spin-echo amplitude responses. Again as with T_1, only relative relaxation signal amplitude response is relevant for T_2 measurements; NMR response signal amplitude *per se* formed no part of the Damadian cancer screen. (Patent at 4/61-65 and Fig. 3 at E. 5 and E. 11, respectively; Lufkin A. 616a-623a, 725a).

** "Qualitative" cancer detection (x-ray images requiring physician evaluation of "indirect evidence" of displacement of normal anatomy) is expressly disparaged by the patent in favor of Damadian's *quantitative* measurements (patent 1/12-21, E. 4).

† Dr. Lufkin was careful to use the word "computing", stating that it was impossible to measure relaxation times. (A. 595a-596a, 610a, 702a-703a). Please see the District Court's Opinion at p. 13, A. 23a.

of known malignant tissue and known normal tissue to establish standard values for the respective tissue conditions; and then measuring the T_1 and T_2 times of tissue to be evaluated. If the NMR T_1 and T_2 times measured for the unknown match the malignant values, the unknown tissue is classified as malignant. If the measured values for the unknown tissue correspond to normal tissue, the specimen is deemed normal. (Damadian S.A. 24-27; Lufkin A. 609a-612a; Olsen (NIH) A. 512a-513a; 518-521a).* **

This is the *only* tissue evaluating/cancer detecting methodology disclosed in the patent. There is no disclosure whatever of (i) imaging, any synonym or equivalent of imaging, or image evaluation (Damadian A. 277a-281a; Lufkin A. 615a-617a, 679a-682a, esp. 679a-680a); (ii) any detection of any abnormality other than cancer (Damadian A. 265†); (iii) using signal "intensity" or any other NMR signal parameter for cancer detection (or

* The patent discloses that the comparison—always quantitative for definitive cancer identification may proceed either manually (col. 5/56-6/46 at E. 6) or via the use of a computer (Fig. 1, patent 6/46-8/12 at E. 10 and E. 6-7, respectively). In each case, the numerical T_1 and T_2 relaxation time values are ***numerically compared*** with predetermined numerical time standards for normal and cancerous tissue. (See as illustrative, Damadian S.A. 24-27; or Lufkin A. 609a-612a).

** Moreover, the patent says that the degree of malignancy of a cancer can be determined by measuring the amount by which the T_1 and T_2 relaxation times exceed the healthy tissue norm (e.g., patent at 1/17-13 and 56-60 at E. 4).

† "Q. Now, Dr. Damadian, on several occasions referring to parts of the patent, you mentioned detecting any kind of abnormality or anomaly or, for that matter, any abnormality other than cancer that is a departure from normal human anatomy.

Is there any statement in this patent that it is usable for detecting any abnormality or condition other than cancer?

A. No."

any other purpose) other than the T_1 and T_2 *relaxation times* (Damadian A. 241a-242a, 245a-251a; Lufkin A. 605a-606a, 616a-623a, esp. 616a-617a); or (iv) finding cancer other than by comparing the T_1 and T_2 relaxation time values for a specimen against standard (reference) T_1 and T_2 times for healthy and cancerous time standards (Damadian A. 93a-104a; 244a-247a).

Claim 1 of the Damadian patent in suit is in accord with his patent specification:

> "1. A method for detecting cancer comprising:
>
> (a) measuring and establishing standard NMR spin-lattice relaxation times and spin-spin relaxation times for both normal and cancerous tissue of the type under analysis using as an indicator nuclei at least one nuclei which exhibits deviant behavior in cancerous tissue;
>
> (b) measuring the NMR spin-lattice relaxation times and spin-spin relaxation times for the suspected tissue to determine the extent of deviant behavior of the indicator nuclei; and
>
> (c) comparing the measured values obtained in (b) against the standards obtained in (a)."

To this claim 2 merely supplies the further limitation that:

> "2. The method of claim 1, wherein the indicator nuclei are cell water protons."

As above noted, "spin-spin relaxation time" simply means T_2; "spin-lattice relaxation time" simply means T_1. The claim language precisely accords with the meaning given the terms used in the patent specification. (Damadian A. 238a-243a).

B. The Accused Technicare NMR Imager

Damadian published his NMR rat cancer experiments in *Science* in March 1971 (PX-22, E. 28) and the patent in suit issued in 1972. Commercial NMR imagers, however, were not offered until about 1980 after a decade of development (Damadian S. A. 28), and do not accord even remotely with the T_1 and T_2 NMR cancer detection teachings or claims of the '832 patent.* The accused Technicare "Teslacon" NMR imaging system—and that of other NMR vendors including plaintiff Fonar, includes apparatus for measuring (and displaying) the amplitude (or "intensity") of the NMR signal (*not* the T_1 and/or T_2 relaxation times) computed for each local area ("pixel") of the cross-sectional plane of a subject to be viewed. (Lufkin A. 634a-638a, 641a-643a, 645a-647a, 728a-729a; Damadian A. 289a-290a).

The seminal contribution making NMR imaging possible was the work of Professor Lauterbur who taught that magnetic field gradients (strength variations) could be used to separately measure the NMR amplitude signal at each spatial location (pixel) in the cross-section.** (Bloom (Pres., NMR of America) A. 324a). Since tissue of different types (without regard to cancer or its absence) generate

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* Judge Keeton found as a matter of law in granting defendants' motion for JNOV that the accused Technicare equipment did not satisfy *any* of the recitations of claim 1 much less the requisite *all* limitations (pp. 14-16 *infra*).

** Dr. Lauterbur has received many awards recognizing his NMR work—most recently the National Medal of Science (authorized by Congress in 1959 as the nation's highest award for achievement in science and technology) for "first proposing and demonstrating the use of nuclear magnetic resonance to form images" (New York Times, June 26, 1987, §A, at 13, col. 1); and the 1987 IEEE Medal of Honor (PR Newswire, June 17, 1987).

different signal NMR amplitude responses, displaying the ensemble of pixel values provides an image of the subject. (Damadian A. 290a; Lufkin A. 617a, 634a-635a, 638a, 641a-643a, 728a-729a).*

The record is replete with images of the parties, e.g., for Technicare, PX-225, 226, E. 247-263 and for Fonar, PX-410, E. 567-570. The NMR amplitude signal, characterizing differing tissue type and condition (e.g., bone, vascular material and/or whatever is present at the corresponding small local pixel areas), modulates a swept cathode ray tube television beam to generate the cross sectional image. (Lufkin A. 634a, 638a, 647a). The beam-modulating measured intensity values are arbitrarily scaled to increase image contrast. That is, the image amplitude value at any point in the display is relative and arbitrary, and depends upon the maximum and minimum amplitude values anywhere in the image. The overall image contrast is thus increased in a manner directly analogous to the contrast control on a television set. (Lufkin A. 614a-615a, 634a-658a, esp. 652a-658a).

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* The Petition postulates the patented Damadian work as "a revolutionary method of detecting cancer in the human body" (p. 3) representing "the most important recent breakthrough in the war on cancer" (p. 4)—all without record citation. The record belies any such contribution. Dr. Damadian's NMR research was immediately published in *Science* in March, 1971 (PX-22, E. 28-31) and the patent issued early in 1974. These and later presentations (e.g., PX-35, E. 63; PX-36, E. 72; PX-37, E. 81; PX-38, E. 89) were viewed by the medical art with "skepticism, even ridicule." (Petitioners' Brief before the CAFC, pp. 1, 18; Damadian A. 141a-2a; 513a- 21a; 533a-35a; 1021a-25a). Indeed, petitioners' trial evidence attempted to sponsor and promote this rejection of Dr. Damadian's work by the scientific community into some *sui generis* indicia of invention. Regretfully, the Damadian 1971 *Science* paper and the '832 patent notwithstanding, no technology yet exists for an NMR (or any other) scan to detect cancer.

What the displayed NMR signal does in commercial imaging equipment, and all it does, is present an image of all internal anatomy for inspection. Physical abnormalities, if any, are hopefully recognized by the physician who knows from education and experience *de hors* the image what internal human structure should look like at the imaged plane.

The image, of course, may present normal anatomy. Any observed physical aberrations, if present, *cannot* be characterized as cancer rather than MS plaque, edema, cyst, benign tumor or even bruises, among the myriad of other non-malignant abnormalities, via the NMR image. Damadian A. 211a, 217a-221a; Lufkin A. 663a-664a; Alfidi (Cleveland University Hospital) A. 352a-355a, 358a-360a; Dr. Brady (Massachusetts General) A. 401a-402a; Dr. Olsen (NIH) A. 541a; O'Brien (Investigational Program Specialist, Technicare) A. 431a). Thus, cancer detection requires a post-image surgically removed tissue biopsy to distinguish cancer from the myriad of other possibilities for the imaged abnormality. (Damadian A. 211a; Lufkin A. 663a-664a, 669a; Olsen A. 541a-542a; Alfidi A. 353a).

Indeed, imaging aside, cancer cannot be distinguished from other abnormalities using the patented T_1 and T_2 relaxation time measurements and comparisons because all have overlapping elevated T_1 and T_2 values. (Lukkin A. 467a; 581a, 708a-714a, esp. 713a-714a*, 736;

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* As Dr. Lufkin testified:

"Q. Let's see what would happen if we had an NMR, pulsed NMR spectrometer, sitting in the operating room. If we removed the tissue, apparently by the T-1 and T-2 values that

(footnote continued on next page)

Meany A. 381a-382a*, 385a-386a; Damadian A. 210a-213a; esp. 210a**; 223a-233a, esp. 228a; 267a-269a, esp. 169a, 217a-

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we measured, we would be able to tell whether it was a normal range or higher than the normal range. Is that so?

A. Yes.

Q. But that if it were higher than the normal range, what we couldn't tell is whether it was edema or multiple sclerosis or other things?

A. In most cases that's correct, yes.

Q. So, that *would not be a good instrument* to have in an operating room *to make a decision on whether something is declared malignant or not?*

A. *I think in spite of everyone's hope it would be, presently it's not capable of that.*" (A. 713a-714a, emphasis added).

* Q. "Doctor, in response to questions from Mr. Nelson, you indicated that you were aware of some work that Dr. Damadian had done in the early 1970's. What work was that?

A. It essentially was work where he looked at relaxation, T-1 and T-2, maybe just T-1 measurements, in vitro in various tumors and concluded that these measurements provided the ability to distinguish benign and malignant tumors.

Q. In your work here at Cleveland Clinic Foundation, have you had any occasion to attempt to assess the validity of Dr. Damadian's results?

A. Yes.

Q. What, if any, conclusions did you reach?

A. Our conclusions are that we cannot verify his work, in that we find the relaxation measurements are useless in specific diagnosis.

Q. Did you find that the measurement was useless to diagnose cancer?

A. Yes.

Q. Whether or not Dr. Damadian's work dealt with T-2, did you have occasion to consider whether the T-2 measurement was of any use in diagnosing cancer?

A. Yes.

Q. What, if any, conclusions did you reach?

A. *It was not of use.*" (A. 381a-382a, emphasis added).

** Dr. Damadian testified:

"Q. Now, let's suppose I conducted an NMR measurement and I got a T1 value of .827—that is a T1 value. And a T2 value

(footnote continued on next page)

274a; Alfidi A. 358a-360a; Brady A. 401a-402a—all witnesses offered by petitioners).

Apropos the patent claims, the accused Technicare NMR imagers do not measure the T_1 or T_2 relaxation time of any unknown as any part of normal image formation.* (Damadian A. 292a-293a; Bloom (NMR of America) A. 328a; Opinion pp. 6-7, 14-17 A. 16a-17a, 24a-27a). Indeed, the Teslacon equipment does not provide any T_2 relaxation time at all. (LufkinA. 733a).

Further, the Technicare equipment does not measure or store any T_2 standard for healthy tissue, or T_1 or T_2 standard for cancerous tissue. That is, no T_2 relaxation time standards are measured or stored; no signal amplitude reference ranges are measured or stored for healthy or cancerous tissue; nor are any other reference values for cancerous tissue stored. (Lufkin A. 733a). *A fortiori*, the Technicare equipment does not make any comparison between non-measured T_1, T_2 (or amplitude) values for the

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of .119. Would you tell me that that specimen of this unknown rat's liver, was that cancerous or was that healthy tissue?

A. Well, I would say two things. I would say it wasn't healthy because the T1 was elevated. And I would say you would have to, among other possibilities have to consider cancer as one of them. There are other situations that could elevate the T1." (A. 210a).

* T_1 values can be derived by using an optional, rarely employed T_1 package to form a T_1 map—but this is no part of normal image development and certainly no part of any practice of the cancer detecting claims. T_2 values can be computed if one desires only by using a series of images followed by manual computation, equipment alteration or the like not taught, suggested or authorized by Technicare. (Lufkin A. 1122a-1123a; Opinion pp. 6, 13, A. 16a 23a). The *sui generis* Lufkin T_2 calculation, for example, required four pulse sequences yielding four different images and a hand-plotted graph to determine a time constant, consuming at least five minutes, for T_2 at a single point. An image, of course, has tens of thousands of such points. (Lufkin A. 1121a-1122a; Damadian A. 186a).

tissue to be evaluated and the non-existent T_1, T_2 (or amplitude) "standards" for healthy, malignant, or any other tissue. (Lufkin A. 657a-664a and 661a-663a; cf. Damadian A. 292-293a, referring to any imaging equipment including Fonar's). Simply stated, as a matter of uncontested predicate fact, there is no signal value quantitatively measured for any part of the patent which is comparable with or in fact compared to any predetermined quantitative standard for any purpose, much less for the cancer determining purposes of the subject Damadian patent.

C. The District Court's Opinion Granting Judgment Notwithstanding The Verdict

District Judge Keeton rejected plaintiffs-appellants' argument that *any* (much less the requisite *all*) of the material '832 claim recitations were infringed by the accused Technicare NMR imagers. (630 F.Supp. 581 (D.Mass. 1986)). Plaintiffs-appellants' meanings ascribed to the several clauses of the patent claims in suit were deemed "truly extraordinary", "impermissible," and "beyond the scope of any permissible interpretation that a reasonable person could accept." (Opinion pp. 14-15, P.A. 24a).

Claims 1 and 2 were characterized (accurately) as including the recitations:

> 1. " 'measuring and establishing *standard*' values for T_1 and T_2 in cancerous and in normal tissues," (emphasis in original, Opinion, p. 15, A. 25a);
>
> 2. " 'measuring' T_1 and T_2 for suspected tissue"; *id.*, and

3. " 'comparing the values' for the suspected tissue 'against the *standards*' for healthy and cancerous tissue" (Opinion, p. 15, P.A., emphasis in original).

As to the first of those claim limitations the Court observed:

> "But not even the most experienced and sophisticated users of NMR scanning apparatus practice the first of the method steps described in Claims 1 and 2—that is, 'measuring and establishing standard' NMR spin-lattice (T_1) relaxation times and standard spin-spin (T_2) relaxation times for both cancerous tissues and healthy tissues of the type under analysis. Indeed, the evidence would not support a finding that anyone has yet established any T_1 and T_2 standards for cancerous and healthy human tissues. Efforts to do so have revealed a phenomenon that T_1 and T_2 values of cancerous tissues of some types overlap significantly with T_1 and T_2 values for normal tissues of other types (and perhaps even to a substantial extent with normal tissues of the same type). There was *no evidence* offered at this trial to support a finding that anyone has yet been able to solve this problem of overlapping and compile standard values that could be used in detecting cancer by the method described in Claims 1 and 2." (Emphasis added; Opinion, pp. 15-16, P.A. 25a).

As to the second and third claim passages noted above, the Court held:

> "[T]here is *no evidence* to support a finding that users practice either the second step (of Claims 1 and 2) of measuring the T_1 and T_2 relaxation times of suspected tissue or the third step of comparing the measurements for the suspected tissue with the standards for healthy and cancerous tissues.

> The argument becomes a distortion of common sense meaning when plaintiffs assert that a diagnostician is 'measuring and establishing standard' NMR relaxation times when, with accumulated experience, the diagnostician learns to draw inferences from the shapes of images observed during extensive experience, stores in personal memory those images as standards, and then compares the standards with the images seen as the diagnostician examines suspected tissue for the purpose of detecting cancer. The words of Claims 1 and 2 will not bear the interpretation plaintiffs thus place upon them to make them so sweeping that they cover all uses of NMR imaging apparatus to detect cancer. Perceptive and pioneering as the patent application may have been, it cannot reasonably be read as a forecast of NMR imaging. The evidence will not support an interpretation of what users of NMR imaging apparatus do that describes their use as 'measuring and establishing standard' NMR T_1 and T_2 relaxation times for both cancerous tissues and healthy tissue of various types, then measuring T_1 and T_2 of suspected tissue, and finally comparing these measured values with the standards." (Emphasis added; Opinion, pp. 15-17, P.A. 25a-26a).

In as clear a way as words can communicate, the District Court ruled against plaintiffs-petitioners on *each* of the claim limitations finding *no evidence* of infringement of any part of the claims, and expressly said so.

Judge Keeton observed the operative criteria to be that "when the court is convinced: . . . that reasonable persons could not in light of the evidence have found the facts necessary to support the jury's verdict"; and that "all instances of allowable differences of interpretation by reasonable persons must be resolved in plaintiffs' favor". (Opinion p. 10, P.A. 21a and again at 22a).

D. Affirmance By The Court Of Appeals

When affirming JNOV (821 F.2d 627 (1987)), the Court of Appeals noted that plaintiffs/petitioners "must show that there was substantial evidence to support the jury's findings". " 'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review. *Perkin-Elmer Corp.* v.*Computervision Corp.*, 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed.Cir.), *cert. denied*, 469 U.S. 857 (1984)." (S.A. 7a).

Rather than the cavalier, "four sketchy page" approach suggestion at p. 11 of the Petition, the CAFC "carefully reviewed all the 'substantial evidence' " petitioners cited in their brief and found "none of the cited testimony is about infringement of a properly interpreted claim." (S.A. 9a). The CAFC then noted that in addition to no testimonial evidence, there was also no extrinsic evidence of infringement—nor even an argument in support of any such evidence. (S.A. 9a).

The CAFC observed that plaintiffs/petitioners had "pointed to no evidence that supports" their theory of infringement. (P.A. 10a). "[R]easonable jurors, after reviewing all the evidence, could not have found claims 1 and 2 of the '832 patent to have been infringed by employment of the mental images and experience of the users of J&J's NMR machines. Judge Keeton properly granted JNOV. *Bio-Rad*. 739 F.2d at 613, 222 USPQ at 661." The CAFC summarized their conclusion:

> "We conclude that the district court correctly determined that no evidence, and thus no substantial evidence, supports a finding that users of J&J's ma-

chine practice the method of claims 1 and 2 of the '832 patent. The jury's verdict that J&J infringed and induced infringement of those claims therefore cannot stand." (Emphasis in original, P.A. 8a).

The Court of Appeals also vacated those portions of the District Court's Judgment holding claims 1 and 2 valid and holding them enforceable. (Opinion, P.A. 12a-13a).

Reasons for Denying the Petition

A. The Courts Below Applied The Correct Preemptive Decision Standard

This Court has recently noted that ". . . the standard for a directed verdict under Federal Rule of Civil Procedure 50(a), which is that the trial judge must direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict. *Brady* v. *Southern R. Co.*, 320 US 476, 479-480, (1943)."* *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242 (1986). "[R]ecent decisions of high authority have established a more reasonable rule, that in every case, before the evidence is left to the jury, there is a preliminary question for the judge, not whether there is literally no evidence, but whether there is any upon which a jury could properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed. . . . See also *Pleasants* v. *Fant*, 22 Wall 116, 120-121 (1875); *Coughran* v. *Bigelow*, 164 U.S. 301, 307 (1896); *Pennsylvania R. Co.* v. *Chamberlain*, 288 U.S. 333, 343 (1933)." *Anderson, supra*, 91 L.Ed. 2d at 213.

* The petitioners (n. 8 at p. 12) correctly note that the standards for a motion for JNOV are the same as for a directed verdict. *U.S. Industries, Inc.* v. *Blake Construction Co.*, 671 F.2d 539, 550 (D.C. Cir. 1982).

This was precisely the approach and standard which both the District Court (pp. 14-16, *supra*) and Court of Appeals (pp. 17-18, *supra*) said was appropriate and which they followed. Each court looked for substantial evidence upon which a jury could reasonably find infringement; and did not find it (or, indeed, *any* such evidence).

The case was properly decided; and the Petition should be denied.

B. The District Court And Court Of Appeals Applied the JNOV Standard Suggested By Plaintiffs-Petitioners; Petitioners' Belated Reversal Of Position

Petitioners recite authorities which differently express the evidence considered in deciding a preemptive motion. Petitioners *now* support a rule that "only the evidence favoring the nonmoving party . . . should be considered" and that "[a]ny evidence produced by the prevailing party must be disregarded." Petition at pp. 13-14 quoting from *Dace* v. *ACF Industries, Inc.*, 722 F.2d 374, 376 (8 Cir. 1983), *reh'g denied*, 728 F.2d 976 (8 Cir. 1984); cf. *Wilkerson* v. *McCarthy*, 336 U.S. 53, 57 (1948). Those authorities which "hold that all of the evidence may be considered on a motion for a directed verdict or for judgment NOV" are now viewed as incorrect. Petition, p. 14 and the authorities set forth at pp. 15-16.*

* The Petition postulates this as a conflict among the Circuits. Semantic differences on point appear as readily within as between Circuits. Please compare, for example, *Kingston* v. *McGrath*, 232 F.2d 495, 497 (9 Cir. 1956) with *M.A.P. Oil Co.* v. *Texaco, Inc.*, 691 F.2d 1303, 1306 (9 Cir. 1982); *Lohr* v. *Tittle*, 275 F.2d 662, 664 at n. 1 (10 Cir. 1960) with *Oldenburg* v. *Clark*, 489 F.2d 839, 841 (10 Cir. 1974); and *Lyons* v. *J.C. Penney Co.*, 316 F.2d 753 (7 Cir. 1963) with *Hannigan* v. *Sears, Roebuck and Co.*, 410 F.2d 285, 288 (7 Cir.), *cert. denied*, 396 U.S. 902 (1969).

Petitioners took the opposite view—and looked to all the evidence—in each court below. In their Response opposing defendants' motion for judgment notwithstanding the verdict before the District Court, petitioners noted (p. 6) "the standards or guidelines which a District Court is to follow" was to not set aside a jury verdict if supported by "substantial evidence." "Substantial evidence" was then defined by petitioners (Response, pp. 6-7):

> " 'Substantial' evidence is such relevant evidence *from the record taken as a whole* as might be accepted by a reasonable mind as adequate to support the finding under review. *Loyce E. Hayes* v. *Department of the Navy*, 727 F.2d 1535 at 1537 (Fed. Cir. 1984); *SSIH Equipment S.A.* v. *USITC*, 718 F.2d 365, 371 n. 10, 218 USPQ 678, 684 n. 10 (Fed. Cir. 1983). In sum, only when the court is convinced *upon the record before the jury* that reasonable persons could not have reached a verdict for the non-mover, should it grant the motion for JNOV." (Emphasis added).

The Response then proceeded with literally dozens of citations to parts of the record introduced by defendants in the case in their search for "substantial evidence" in the "record as a whole."*

Petitioners repeated this theme before the Court of Appeals. In their Brief before the CAFC, in the section captioned "Scope of Appellate Review and The Legal Standards For JNOV" (pp. 23-27), petitioners again noted the requirement for "substantial evidence" and again defined it as "such relevant evidence from the *record taken as a whole* as might be accepted by a reasonable mind as ade-

* In its "Conclusion On Infringement" before the District Court, petitioners again observed the appropriate inquiry to include "considerations to *all the evidence*." (Response, p. 51, emphasis added).

quate to support the finding under review." (Brief, pp. 24-25, emphasis added). Petitioners again had extensive citations to respondents' evidence and, moreover, noted that the District Court invoked "the proper legal standard" (p. 38) although quarrelling with its application.

Having directed both the District Court and the CAFC to review the entire record in their unsuccessful quest for substantial evidence to support the jury verdict petitioners should not be heard now to *nunc pro tunc* deem this error and seek the opposite rule. *Maxwell Land Grant Co.* v. *Dawson,* 151 U.S. 586, 606 (1894), *St. Louis Public Schools* v. *Risley,* 77 U.S. 91, 114 (1869); Cf. *Hoover* v. *Ronwin,* 466 U.S. 558, 574 at n. 25 (1984), *Heath* v. *Alabama,* 474 U.S. 82, 88 L.Ed.2d 387, 393 (1985); *Springer* v. *United States,* 102 U.S. 586, 593 (1880). Please see also Rule 46, Fed.R.Civ.P., and its progeny requiring that "at the time [an] order of the court is made" the party must make "known to the court the action which [he] desires the court to take. . . ."* All Courts below invoked the JNOV standard as petitioners would have it.

C. There Is No Standard Of Review Which Would Help Petitioners Here

This case is not a likely candidate to resolve differences, if any, in the determination of JNOV. Whether only plaintiffs' evidence, or all evidence, is evaluated, both the District Court and the CAFC held there was *no* evidence

* The principal reason, of course, is that the "purpose of Rule 46 is to inform the trial judge of possible errors so that he may have the opportunity to consider his rulings and correct them if necessary." *Codex Corp.* v. *Milgo Electronics Corp.,* 717 F.2d 622, 629 (1 Cir. 1983), *cert. denied,* 466 U.S. 931 (1984); 9 C. Wright & A. Miller, Federal Practice and Procedure § 2472 at 454-56 (1971).

in the record to support petitioners' claim of infringement. Thus, petitioners cannot prevail under any appropriate standard.*

Indeed, petitioners' entire premise lacks logic. All concerned—each of the parties and each court below—agree that judgment NOV is not warranted if the jury verdict is supported by substantial evidence. Petitioners as the nonmoving party are aided, not penalized, if the entire record can be searched for such evidence.**

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* The Petition emphasizes a quotation from *Wilkerson* v. *McCarthy*, 336 U.S. 53 (1949) which supports review of evidence favoring the nonmoving body on a preemptive motion. Of course, that is precisely what both courts below did in resolving this case. Whether *Wilkerson* v. *McCarthy* states some *sui generis* rule for federal employees' liability cases is apparently a matter of some controversy. 9 C. Wright & A. Miller, Federal Practice and Procedure § 2529 (1971) and please see *Boeing Co.* v. *Shipman*, 411 F.2d 365 (5 Cir. 1969). This is not a FELA case. Moreover even in FELA cases, preemptive judgment, whatever the operative standard, is appropriate where there is "no evidence" supporting the nonmoving party. *Moore* v. *Chesapeake & Ohio Railway Co.*, 340 U.S. 573, 578 (1950).

** The Petition (p. 17) cites evidence in the *record* unfavorable to its cause—and suggests that the JNOV outcome would have been different if this testimony of Dr. Waugh were not considered. The short answer is that neither this passage, nor any other unfavorable evidence caused JNOV to be granted or affirmed. Petitioners' problem below was not the *presence* of unfavorable evidence (of either party) but, rather, the *absence* of evidence of either party which would support infringement. The Lufkin passage (Petition p. 18), and all else relied upon by petitioners below as supposed "substantial evidence", is not evidence of infringement of any part, much less the requisite all, of claims 1 and 2 at issue.

Conclusion

For the reasons above stated, Respondents urge that the Petition for Writ of Certiorari be denied.

Respectfully submitted,

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STEPHEN B. JUDLOWE
HOPGOOD, CALIMAFDE, KALIL,
BLAUSTEIN & JUDLOWE
60 East 42nd Street
New York, New York 10165
(212) 986-2480
Attorneys for Respondents

Of Counsel:
FRANCIS J. MURPHY
EVE KUNEN
HOPGOOD, CALIMAFDE, KALIL,
BLAUSTEIN & JUDLOWE
60 East 42nd Street
New York, New York 10165